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Governor Mitchell E. Daniels, Jr.

Board of Pharmacy Study on the Application of Technology in Dispensing Drugs

As Required by P.L.94-2007, SECTION 4

November 1, 2007

The Indiana board of pharmacy ("board") was charged under P.L.94-2007, SECTION 4, with the duty to study and make findings on the issue of the application of technology in the dispensing of drugs, including the reliance on bar code technology in long term care pharmacies. The study must include the review of the use of pharmacy technicians when using bar code technology.

The board's findings, recommendations and suggestions on the use of technology in dispensing medications are hereby submitted to the Health Finance Commission and Legislative Council and discussed below.

Introduction. The well-established and respected role of the pharmacist in dispensing medications to patients has been trusted to the pharmacy profession for centuries. The expertise, education and training of pharmacists for these responsibilities have been over seen by the board for over one hundred (100) years. For most of that century the profession has had very little change in the overall day-to-day function of the practicing pharmacist. The rapid advances in technology and automation of the late 1990's and ongoing in the 2000's has led to questions as to whether there is a better and more accurate way to fulfill the manual dispensing function. The board was mandated to review the application of technology in dispensing drugs with special emphasis on technician roles when coupled with bar coding in long term care pharmacies.

To accomplish this task, the board held a meeting of stakeholders on September 5, 2007 to discuss current practices, technologies available in the dispensing process and current and future roles of technicians and pharmacists in light of the technology. Board members visited several facilities that were currently using state of the art new technological advances to see and discuss with the professional staff the advantages and concerns experienced from working with the new technology. Lastly the board did a literature search to discover what was being published by the national experts in the fields of technology and subsequent change of technician roles.

Note that the board is presently promulgating rules for automated medication dispensing systems that will provide guidance for the use of technology in dispensing medications. The rule, as presently drafted, will require such systems to implement quality assurance

measures. The rule also defines responsible parties and requirements necessary to utilize automated systems including retention of records, inspection and error reporting.

This report summarizes the conclusions and recommendations of this board and most of the participating stakeholders.

1. Decrease in medication errors. The implementation of bar code technology to provide an additional quality check of a prescription has been shown to decrease errors. The use of this technology must include an active and closely measured quality assurance program (as is required by the draft rule referenced above). Bar coding, as an individualized function without practitioner involvement and a quality assurance program, provides very little assurance of a safely filled prescription.

2. Bar coding of repackaged medications. Bar codes are required by the Food and Drug Administration ("FDA") on all medications; however, the bar code is not required on many of the unit-of-use products. This bar code inconsistency has the potential of creating an unhealthy sense of security if not closely monitored. This board suggests that should the individual patient medication unit not be coded and must be repackaged to provide that bar code, that the repackaging be done prior to its arrival in the dispensing area and that coding be done by another set of pharmacy professionals.

3. Bar code scanning of multiple open units of medication. If multiple open units of a medication are placed within a single prescription, each of those units must be scanned to assure all are correct. If the medication unit is still under the unopened seal of the manufacturer or wholesaler, a scan of the package is appropriate. A study of this process demonstrated that if this was not done, there was a 2.4 fold increase in the incidence of potential adverse drug events.

4. Quality assurance program requirement, responsible parties, error reporting, and annual review. The key to any safe and successful incorporation of technology into patient care services must include an equally active and closely measured and monitored quality assurance program. It is the recommendation of this board that to accomplish this close oversight, a quality assurance program should be a mandatory component of the process. The pharmacy's policies, procedures and reporting of any quality assurance discrepancies or disturbing trends to the board or its representative would be the direct responsibility of this person. The pharmacy shall annually review, and revise as necessary, the quality assurance program with documentation to that effect .

5. Compliance officer training. The board recommends that the board compliance officers be given extensive training in the process of reviewing a pharmacy's quality assurance program. A further recommendation that the Indiana Professional Licensing Agency ("PLA") and compliance officers work with other health quality groups to develop a quality inspection program. The board notes

that this recommendation fiscally impacts PLA's annual budget. It is the board's understanding that the PLA's budget cannot absorb this recommendation based on the present allotment of funds provided to PLA by the general assembly. The board also notes that PLA's present operating budget supports the employment of only four (4) compliance officers at a pay rate of $31,000.00 annual salary for the annual inspection of one thousand four hundred (1,400) pharmacies licensed in the State of Indiana. Due to the complexity and increased technology in the pharmacy community, it is imperative that highly qualified, trained, educated and experienced individuals hold the compliance officer position. With the advent of dispensing technology, compliance officers must be armed with the proper skill set to protect the public health and safety of Indiana citizens. The board takes this opportunity to recommend the allocation of additional resources to PLA and the board of pharmacy to ensure the proper staffing and resources necessary to provide proper regulation of the pharmacy community.

6. Pharmacy technicians & bar code technology. New technology reworks the traditional dispensing model. In some instances, it eliminates the "final check" of a prescription before it is dispensed. Initial concerns about this new model of dispensing revolved around the use of technicians within the system; however, the ultimate issue is not the pharmacy technician role, but the role of the pharmacist as the final check in the drug distribution process. Statute prohibits a pharmacy technician from conducting the final check of any medication being dispensed to a patient. The board interprets this prohibition to mean that only a pharmacist may conduct the final check. The board discussed many current systems and attempted to determine at what point must the final check take place. The final consensus of the board concerning final check is that it is the last point at which the pharmacist requires a professional judgment. From that point forward, the dispensing process must be a closed and consistent process that has a proven safety record. The pharmacy using this process must have proven quality assurance policy and procedures that address deviations or breaks from the defined process. It is imperative that safety testing of new technologies take place until such a time the system is proven safe. The pharmacist must address any breaks or errors in the system immediately. The technician can be part of the technological process but must not be put in the position to deviate from proven safe processes or make a judgment decision within the process.

7. Training of pharmacy professionals utilizing new technology. All pharmacists, pharmacy technicians, and other appropriate staff must be thoroughly trained in the automated process, best practice quality standards, and actions to take if a break/error occurs in the process.

8. Educational training for technicians. To date, no formal educational training is required of pharmacy technicians. The board recommends that a study group of board members and stakeholders evaluate whether formal educational training of technicians would allow for an expansion of technician responsibilities directly tied to an increase in the pharmacist's clinical and patient care responsibilities.

9. Pharmacist-to-pharmacy technician ratio. The current statutory language for pharmacist to technician ratios should be re-examined to determine if a set ratio is still best for patient care. It is clear that differing pharmacy operations may require different ratios based upon what is needed to safely provide patient care. The board recommends that a study group look at current best practice pharmacy models, safety data from national groups such as the Institute for Safe Medication Practices ("ISMP") and the Agency for Healthcare Research & Quality ("AHRQ"), and a review of current abuses of the statute to determine if a safety standard for ratios can be individualized per pharmacy site. *It is imperative that if a flexibility of ratios is granted, there must be quality safety standards in place and that the pharmacy compliance officers are granted the education and training needed to evaluate the pharmacy for its safety practices.*

10. Remote order entry. The medical community's and patient's increasing need for a pharmacist's expertise in care, education and medications have resulted in pharmacist shortages in some of the most vulnerable of patient facilities. To meet this need, many pharmacies have implemented the use of technology in terms of a process called "remote order entry". This process allows for an order to be scanned into a computer in one pharmacy/facility and viewed anywhere else in the world for evaluation and processing. Indiana currently allows the general process of remote order entry but has no patient safety standards or visible accountability and responsibility declaration for the processes participants. The board recommends that the issue be given to a study group with subsequent legislation addressing areas including but not limited to patient safety, accountability and legal liability of the remote entry pharmacist, and assuring compliance with patient confidentiality. Evaluation of current pharmacy permits and pharmacist licensure must be included within the context of that discussion.

11. Medication errors. Medication errors and quality related events should be tracked, classified, reported to a national error-reporting database like FDA or ISMP. This information is available to the board and its agents.